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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA AG and JAGOTEC AG, Plaintiffs, v. WATSON LABORATORIES, INC. - FLORIDA, Defendant.	Civil Action No. 13-5124 (JEI/JS) ***Document Electronically Filed***

DEFENDANT WATSON LABORATORIES, INC. – FLORIDA'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendant Watson Laboratories, Inc. – Florida ("Watson") submits the following Answer, Separate Defenses and Counterclaims to Plaintiffs' Complaint ("Complaint"). This Answer is based upon Watson's knowledge as to its own activities and upon information and belief as to the activities of others. The numbered paragraphs below correspond to the paragraphs in the Complaint.

AS TO THE ALLEGED NATURE OF THE ACTION

1. Watson admits that this is an action for patent infringement under Title 35 of the United States Code, and admits that it filed an ANDA with the FDA seeking approval to market a generic version of RAYOS® prior to the expiration of U.S. Patent Nos. 6,488,960 ("the '960 patent"), 6,677,326 ("the '326 patent"), 8,309,124 ("the '124 patent"), 8,168,218 ("the '218 patent") and 8,394,407 ("the '407 patent"). Watson denies the remaining allegations of this paragraph.

AS TO THE ALLEGED PARTIES

2. Watson denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2.

3. Watson denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3.

4. Watson admits that Watson was formerly known as Andrx Pharmaceuticals, admits that Watson is a Florida corporation having a place of business at 4955 Orange Drive, Davie, Florida 33314, and admits that Watson is in the business of, among other things,

developing, manufacturing and obtaining regulatory approval of generic pharmaceutical products for the United States market. Watson denies the remaining allegations of this paragraph.

5. Watson admits that Actavis Pharma, Inc. ("Actavis Pharma") was formerly known as Watson Pharma, Inc., admits that Actavis Pharma is a Delaware corporation having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, and admits that Actavis Pharma is in the business of, among other things, selling and distributing generic pharmaceutical products in the United States market, including products that are manufactured by Watson and/or for which Watson is the named applicant for an ANDA. Watson denies the remaining allegations of this paragraph.

6. Watson admits that Actavis, Inc. ("Actavis") was formerly known as Watson Pharmaceuticals, Inc. ("WPI") until on or around January 24, 2013, admits that Actavis is a Nevada corporation having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, and admits that Actavis is in the business of, among other things, developing, manufacturing, obtaining regulatory approval, marketing, selling and distributing generic pharmaceutical products in the United States market, through the actions of its subsidiaries. Watson denies the remaining allegations of this paragraph.

7. Watson admits that Andrx Corporation ("Andrx") is a Delaware corporation having a place of business at 4955 Orange Drive, Davie, Florida 33314. Watson denies the remaining allegations of this paragraph.

8. Watson admits that WPI acquired Andrx on or around November 3, 2006. Watson denies the remaining allegations of this paragraph.

9. Watson admits the allegations contained in Paragraph 9.

10. Watson admits the allegations contained in Paragraph 10.

11. Watson admits that Actavis organizes its operations by divisions, and reports its financial results in its Securities and Exchange Commission ("SEC") filings by reference to its divisions. Watson also admits that Actavis has consolidated its financial results with its subsidiaries since 2007, and did not file separate financial reports to the SEC for each subsidiary. Watson denies the remaining allegations of this paragraph.

12. Watson denies the allegations contained in paragraph 12.

13. Watson admits that the head of the Generics Division is an employee of Actavis, admits that Watson submits ANDAs and manufactures and develops generic pharmaceutical products for the U.S. market, and admits that Actavis Pharma markets, sells and distributes generic pharmaceutical products in the U.S. market. Watson also admits that Watson and Actavis Pharma are parties to contractual agreements regarding generic pharmaceutical products. Watson denies the remaining allegations of this paragraph.

14. Watson denies the allegations in paragraph 14, but avers that Watson, Actavis Pharma and Actavis have a director and at least one officer in common.

15. Watson will not contest that Watson is within the control of Actavis for the purposes of responding to discovery in this action only, and pursuant to the Stipulation between the parties to this action dismissing Actavis Pharma, Andrx and Actavis. Watson denies the remaining allegations of this paragraph.

16. Watson denies the allegations contained in paragraph 16.

17. Watson admits that it has been a party to at least six prior actions in this Court, and admits that it asserted counterclaims in this Court in *Astrazeneca AB, et al. v. Watson Labs, Inc. – Florida et al.* Civil Action No. 13-1669. Watson denies the remaining allegations of this paragraph.

18. Because Actavis has been dismissed from this case, no response is required. To the extent a response is required, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

19. Because Actavis Pharma has been dismissed from this case, no response is required. To the extent a response is required, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

AS TO THE ALLEGED JURISDICTION AND VENUE

20. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Watson will not contest that this Court has subject matter jurisdiction over this action for purposes of this action only.

21. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Watson will not contest personal jurisdiction in this court for the purposes of this action only. Watson denies the remaining allegations of this paragraph.

22. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Watson does not contest that venue is proper in this Court for purposes of this action only.

AS TO THE ALLEGED PATENTS-IN-SUIT

23. Watson admits that the ’960 patent is titled “Corticosteroid Formulation.” Watson lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them, but avers that the ’960 patent issued on December 3, 2002, that a copy is attached to the Complaint as Exhibit A, and according to the patent assignment database at the U.S. Patent and Trademark Office (“PTO”), was assigned to Arakis, Ltd. (whose name subsequently changed to Sosei R&D Ltd.), and from

Sosei R&D Ltd. to Nitec Pharma AG (whose name subsequently changed to Horizon Pharma AG; "Horizon").

24. Watson admits that the '326 patent is titled "Corticosteroid Formulation Comprising Less Than 2.5 mg Prednisolone for Once Daily Administration." Watson lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them, but avers that the '326 patent issued on January 13, 2004, that a copy is attached to the Complaint as Exhibit B, and that according to the patent assignment database at the PTO was assigned to Arakis, Ltd. (whose name subsequently changed to Sosei R&D Ltd.), and from Sosei R&D Ltd. to Nitec Pharma AG (whose name subsequently changed to Horizon).

25. Watson admits that the '124 patent is titled "Delayed Release Tablet with Defined Core Geometry." Watson lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them, but avers that the '124 issued on November 13, 2012, that a copy is attached to the Complaint as Exhibit C, and that the '124 patent lists Jagotec AG ("Jagotec") as an assignee on its face.

26. Watson admits that the '218 patent is titled "Delayed Release Tablet with Defined Core Geometry." Watson lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them, but avers that the '218 patent issued on May 1, 2012, that a copy is attached to the Complaint as Exhibit D, and that the '218 patent lists Jagotec as an assignee on its face.

27. Watson admits that the '407 patent is titled "Delayed Release Tablet with Defined Core Geometry." Watson lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them, but avers that the

’407 patent issued on March 12, 2013, that a copy is attached to the Complaint as Exhibit E, and that the ’407 patent lists Jagotec as an assignee on its face.

AS TO THE ALLEGED RAYOS® PRODUCT

28. Watson lacks knowledge or information sufficient to form a belief about the truth of the allegations of this paragraph and therefore denies them, but avers that Horizon Pharma is listed as the holder of New Drug Application No. 202020 (“the RAYOS® NDA”) and that the RAYOS® NDA was subsequently approved. Watson also avers that, according to its most recent product label, RAYOS® is a prednisone delayed release tablet having 1 mg, 2 mg and 5 mg strengths, and is indicated as an anti-inflammatory or immunosuppressive agent for certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal, respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation; for the treatment of certain endocrine conditions; and for palliation of certain neoplastic disorders.

29. Watson admits that the ’960, ’326, ’124, ’218 and ’407 patents are currently listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) for the RAYOS® product. Watson lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them.

30. Watson admits that the Orange Book lists the ’960 and ’326 patents for the RAYOS® product in 1 mg and 2 mg dosage strengths, that the Orange Book lists the ’124 and ’407 patents for the RAYOS® product in 1 mg, 2 mg and 5 mg dosage strengths, and that the Orange Book lists the ’218 patent for the RAYOS® product in 5 mg dosage strength. Watson

lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of this paragraph and therefore denies them.

31. Watson denies the allegations contained in Paragraph 31.

AS TO THE ALLEGATIONS REGARDING WATSON'S ANDA

32. Watson denies the allegations of this paragraph, but avers that it seeks the FDA's approval for the ANDA product that is the subject of the Watson ANDA.

33. Watson admits that the Watson ANDA contains data to support bioequivalence between the ANDA product and the RAYOS® product. Watson denies the remaining allegations of this paragraph, but avers that the Watson ANDA refers to and relies on data from the RAYOS® NDA to the extent required by the Drug Price Competition and Patent Term Restoration Act ("the Hatch-Waxman Act") under 21 U.S.C. § 355(j).

34. Watson admits that a letter dated July 15, 2013 ("the 2013 Notice Letter") from Watson was sent to Plaintiffs Horizon Pharma AG ("Horizon") and Jagotec AG ("Jagotec") (collectively, "Plaintiffs") and admits that the 2013 Notice Letter stated that Watson's ANDA included a certification that the claims of the '960, '326, '124, '218 and '407 patents are invalid, unenforceable and/or would not be infringed by the ANDA product (a "Paragraph IV certification"). Watson denies the remaining allegations of this paragraph.

AS TO THE ALLEGED FIRST COUNT FOR INFRINGEMENT: '960 PATENT

35. Watson restates and incorporates by reference their responses to the allegations of paragraphs 1-34 as though fully set forth herein.

36. Watson denies the allegations contained in Paragraph 36.

37. Watson denies the allegations contained in Paragraph 37.

38. Watson denies the allegations of this paragraph, but avers that the 2013 Notice Letter advised Plaintiffs of Watson's Paragraph IV certification with respect to the '960 patent.

39. Watson denies the allegations of this paragraph, but avers that the '960 patent was listed in the Orange Book prior to its sending of the 2013 Notice Letter to Plaintiffs.

40. Watson denies the allegations contained in Paragraph 40.

41. Watson denies the allegations contained in Paragraph 41.

42. Watson denies the allegations contained in Paragraph 42.

43. Watson denies the allegations contained in Paragraph 43.

AS TO THE ALLEGED SECOND COUNT FOR INFRINGEMENT: '326 PATENT

44. Watson restates and incorporates by reference their responses to the allegations of paragraphs 1-43 as though fully set forth herein.

45. Watson denies the allegations contained in Paragraph 45.

46. Watson denies the allegations contained in Paragraph 46.

47. Watson denies the allegations of this paragraph, but avers that the 2013 Notice Letter advised Plaintiffs of Watson's Paragraph IV certification with respect to the '326 patent.

48. Watson denies the allegations of this paragraph, but avers that the '326 patent was listed in the Orange Book prior to its sending of the 2013 Notice Letter to Plaintiffs.

49. Watson denies the allegations contained in Paragraph 49.

50. Watson denies the allegations contained in Paragraph 50.

51. Watson denies the allegations contained in Paragraph 51.

52. Watson denies the allegations contained in Paragraph 52.

AS TO THE ALLEGED THIRD COUNT FOR INFRINGEMENT: '124 PATENT

53. Watson restates and incorporates by reference their responses to the allegations of paragraphs 1-52 as though fully set forth herein.

54. Watson denies the allegations contained in Paragraph 54.

55. Watson denies the allegations contained in Paragraph 55.

56. Watson denies the allegations of this paragraph, but avers that the 2013 Notice Letter advised Plaintiffs of Watson's Paragraph IV certification with respect to the '124 patent.

57. Watson denies the allegations of this paragraph, but avers that the '124 patent was listed in the Orange Book prior to its sending of the 2013 Notice Letter to Plaintiffs.

58. Watson denies the allegations contained in Paragraph 58.

59. Watson denies the allegations contained in Paragraph 59.

60. Watson denies the allegations contained in Paragraph 60.

61. Watson denies the allegations contained in Paragraph 61.

AS TO THE ALLEGED FOURTH COUNT FOR INFRINGEMENT: '218 PATENT

62. Watson restates and incorporates by reference their responses to the allegations of paragraphs 1-61 as though fully set forth herein.

63. Watson denies the allegations contained in Paragraph 63.

64. Watson denies the allegations contained in Paragraph 64.

65. Watson denies the allegations of this paragraph, but avers that the 2013 Notice Letter advised Plaintiffs of Watson's Paragraph IV certification with respect to the '218 patent.

66. Watson denies the allegations of this paragraph, but avers that the '218 patent was listed in the Orange Book prior to its sending of the 2013 Notice Letter to Plaintiffs.

67. Watson denies the allegations contained in Paragraph 67.

68. Watson denies the allegations contained in Paragraph 68.

69. Watson denies the allegations contained in Paragraph 69.

70. Watson denies the allegations contained in Paragraph 70.

AS TO THE ALLEGED FIFTH COUNT FOR INFRINGEMENT: '407 PATENT

71. Watson restates and incorporates by reference their responses to the allegations of paragraphs 1-70 as though fully set forth herein.

72. Watson denies the allegations contained in Paragraph 72.

73. Watson denies the allegations contained in Paragraph 73.

74. Watson denies the allegations of this paragraph, but avers that the 2013 Notice Letter advised Plaintiffs of Watson's Paragraph IV certification with respect to the '407 patent.

75. Watson denies the allegations of this paragraph, but avers that the '407 patent was listed in the Orange Book prior to its sending of the 2013 Notice Letter to Plaintiffs.

76. Watson denies the allegations contained in Paragraph 76.

77. Watson denies the allegations contained in Paragraph 77.

78. Watson denies the allegations contained in Paragraph 78.

79. Watson denies the allegations contained in Paragraph 79.

AS TO THE PLAINTIFFS' PRAYER FOR RELIEF

A. Watson denies that Plaintiffs are entitled to the relief requested in paragraph A.

B. Watson denies that Plaintiffs are entitled to the relief requested in paragraph B.

C. Watson denies that Plaintiffs are entitled to the relief requested in paragraph C.

D. Watson denies that Plaintiffs are entitled to the relief requested in paragraph D.

E. Watson denies that Plaintiffs are entitled to the relief requested in paragraph E.

F. Watson denies that Plaintiffs are entitled to the relief requested in paragraph F.

G. Watson denies that Plaintiffs are entitled to the relief requested in paragraph G.

H. Watson denies that Plaintiffs are entitled to the relief requested in paragraph H.

I. Watson denies that Plaintiffs are entitled to the relief requested in paragraph I.

J. Watson denies that Plaintiffs are entitled to the relief requested in paragraph J.

K. Watson denies that Plaintiffs are entitled to the relief requested in paragraph K.

L. Watson denies that Plaintiffs are entitled to the relief requested in paragraph L.

M. Watson denies that Plaintiffs are entitled to the relief requested in paragraph M.

N. Watson denies that Plaintiffs are entitled to the relief requested in paragraph N.

O. Watson denies that Plaintiffs are entitled to the relief requested in paragraph O.

P. Watson denies that Plaintiffs are entitled to the relief requested in paragraph P.

Q. Watson denies that Plaintiffs are entitled to the relief requested in paragraph Q.

R. Watson denies that Plaintiffs are entitled to the relief requested in paragraph R.

DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations found in the Complaint not otherwise admitted, Watson avers and asserts the following defenses:

FIRST SEPARATE DEFENSE

(Non-Infringement)

The manufacture, use, sale, offer for sale, or importation of the ANDA product has not, does not and would not infringe any valid and enforceable claim of the ’960, ’326, ’124, ’218, or ’407 patents either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

SECOND SEPARATE DEFENSE

(Invalidity)

The claims of the '960, '326, '124, '218, or '407 patents are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112.

THIRD SEPARATE DEFENSE

(Failure To State A Claim)

The Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

FOURTH SEPARATE DEFENSE

(Other Defenses)

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Watson Laboratories, Inc. – Florida ("Watson"), for its Counterclaims against Plaintiffs Horizon Pharma AG ("Horizon") and Jagotec AG ("Jagotec") (collectively, "Plaintiffs"), alleges as follows:

PARTIES

1. Counterclaimant Watson is a Florida Corporation having a principal place of business at 4955 Orange Drive, Davie, Florida 33314.

2. Counterclaim Defendant Horizon purports to be a company organized and existing under the laws of Switzerland, having its principal place of business at Kagenstrasse 17, CH-4153 Reinarch, Switzerland.

3. Counterclaim Defendant Jagotec purports to be a company organized and existing under the laws of Switzerland, having its principal place of business at Eptingerstrasse 61, CH-4152 Muttenz, Switzerland.

JURISDICTION AND VENUE

4. This is a declaratory judgment action under the patent laws of the United States, 35 U.S.C. § 1, *et seq*. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Plaintiffs because, on information and belief, Plaintiffs are actively and regularly engaged in business in the State of New Jersey and derive substantial revenues from things used or consumed in the State of New Jersey.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b). This Court may declare the rights and legal relation of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

BACKGROUND

7. Horizon purports to be the owner of U.S. Patent Nos. 6,488,960 ("the '960 patent") and 6,677,326 ("the '326 patent").

8. Jagotec purports to be the owner of U.S. Patent Nos. 8,308,124 ("the '124 patent"), 8,168,218 ("the '218 patent") and 8,394,407 ("the '407 patent).

9. Horizon purports to be the holder of New Drug Application No. 202020 ("the RAYOS® NDA"), directed to prednisone delayed release tablets in 1 mg, 2 mg and 5 mg dosage strengths, which are sold under the trade name RAYOS® ("the RAYOS® drug product").

10. The '960, '326, '124, '218, and '407 patents are listed in the Orange Book with respect to the RAYOS® drug product that is the subject of Plaintiffs' Complaint.

11. Watson filed ANDA No. 204867 ("the Watson ANDA") with the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, and pursuant to 21 U.S.C. § 355(j), seeking FDA approval to market a proposed prednisone product ("the ANDA product") in the United States. The Watson ANDA included a Paragraph IV certification certifying that the claims of the '960, '326, '124, '218, and '407 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Watson's ANDA.

12. In accordance with 21 U.S.C. § 355(j)(2)(B), Watson sent a letter to Plaintiffs on July 15, 2013 ("the 2013 Notice Letter") notifying each of them that it had filed the Watson ANDA with a Paragraph IV certification stating that the claims of the '960, '326, '124, '218, or '407 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Watson's ANDA.

13. On or about August 26, 2013, Plaintiffs filed a Complaint for patent infringement alleging that Watson's submission of the Watson ANDA infringes the '960, '326, '124, '218, and '407 patents under 35 U.S.C. §271(e)(2)(A).

14. A definite and concrete, real and substantial, justiciable controversy exists between Plaintiffs and Watson with respect to the validity and infringement of the '960, '326, '124, '218, and '407 patents, which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

COUNT I

(Declaratory Judgment of Invalidity of the '960 Patent)

15. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-14 as though fully set forth herein.

16. Upon information and belief, the claims of the ’960 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and 112.

COUNT II

(Declaratory Judgment of Non-Infringement of the ’960 Patent)

17. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-16 as though fully set forth herein.

18. Watson has not and will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’960 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of the ANDA product, or by meaningful preparation to manufacture, use, market, or sell the ANDA product in the United States.

COUNT III

(Declaratory Judgment of Invalidity of the ’326 Patent)

19. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-18 as though fully set forth herein.

20. Upon information and belief, the claims of the ’326 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and 112.

COUNT IV

(Declaratory Judgment of Non-Infringement of the ’326 Patent)

21. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-20 as though fully set forth herein.

22. Watson has not and will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’326 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of the ANDA product, or by meaningful preparation to manufacture, use, market, or sell the ANDA product in the United States.

COUNT V

(Declaratory Judgment of Invalidity of the ’124 Patent)

23. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-22 as though fully set forth herein.

24. Upon information and belief, the claims of the ’124 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and 112.

COUNT VI

(Declaratory Judgment of Non-Infringement of the ’124 Patent)

25. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-24 as though fully set forth herein.

26. Watson has not and will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’124 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of the ANDA product, or by meaningful preparation to manufacture, use, market, or sell the ANDA product in the United States.

COUNT VII

(Declaratory Judgment of Invalidity of the ’218 Patent)

27. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-26 as though fully set forth herein.

28. Upon information and belief, the claims of the ’218 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and 112.

COUNT VIII

(Declaratory Judgment of Non-Infringement of the ’218 Patent)

29. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-28 as though fully set forth herein.

30. Watson has not and will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’218 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of the ANDA product, or by meaningful preparation to manufacture, use, market, or sell the ANDA product in the United States.

COUNT IX

(Declaratory Judgment of Invalidity of the ’407 Patent)

31. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-30 as though fully set forth herein.

32. Upon information and belief, the claims of the ’407 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and 112.

COUNT X

(Declaratory Judgment of Non-Infringement of the ’407 Patent)

33. Watson restates and incorporates by reference the allegations set forth in paragraphs 1-32 as though fully set forth herein.

34. Watson has not and will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’407 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of the ANDA product, or by meaningful preparation to manufacture, use, market, or sell the ANDA product in the United States.

PRAYER FOR RELIEF

WHEREFORE, Watson respectfully requests that the Court enter an order:

A. Dismissing the Complaint with prejudice;

B. Declaring that Watson’s proposed ANDA product that is the subject of the Watson ANDA will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’960, ’326, ’124, ’218, or ’407 patents under 35 U.S.C. § 271;

C. Declaring that the claims of the ’960, ’326, ’124, ’218, and ’407 patents are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 102, 103 and/or 112;

D. Declaring this case exceptional and awarding Watson reasonable attorneys’ fees and costs under 35 U.S.C. § 285;

E. Awarding Watson its costs; and

F. Awarding Watson such other further relief as the Court deems just and equitable.

Respectfully submitted,

SAIBER LLC
Attorneys for Defendant/Counterclaim-Plaintiff
Watson Laboratories, Inc. -Florida

Dated: November 12, 2013 By: /s/ Arnold B. Calmann

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

On behalf of defendant/counterclaim-plaintiff Watson Laboratories, Inc. - Florida, I hereby certify that the following actions are related: *Horizon Pharma AG and Jagotec AG v. Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.*, Civil Action No. 13-cv-6298 (JEI/JS) (D.N.J.).

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court in this jurisdiction, or of any pending arbitration or administrative proceedings.

Dated: November 12, 2013 By: /s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)

CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for defendant/counterclaim-plaintiff Watson Laboratories, Inc. – Florida ("Watson") hereby certifies that Watson seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: November 12, 2013 By: /s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)